Memo of Meeting

Date: March 30, 2001

Location: Rockville, MD

Subject: Implementation of 21 Code of Federal Regulations, Part 11; Electronic Records; Electronic Signatures; Scope of the rule

Representing the Industry Coalition on 21 CFR Part 11:

Mr. William Bradley, Vice President, Technical Affairs, Consumer Health Care Products Association

Mr. Christopher Allen, Vice President. Operations, Northern Americas Region, Bayer Corporation

Mr. Bernie Liebler, Director, Technology & Regulatory Affairs, Advanced Medical Technology Association

Mr. Dave Everson, IT Management Solutions, Inc.

Mr. Will Robinson, Staff VP, CR Bard, Inc.

Mr. Johnny Long, Director, Quality Management, Baxter Healthcare Corp.

Mr. Philip Loftus, Senior Vice President, Global Strategy & Applications, Pharmaceutical Research and Manufacturers Association/Glaxo Smith Kline

Mr. Krishan Arora, Vice President Technical Operations, Pharmacia

Representing the Food and Drug Administration, FDA Part 11 Compliance Committee:

Mr. John Taylor, Director, Office of Enforcement

Mr. Paul J. Motise, Consumer Safety Officer, Office of Enforcement

Dr. James McCormack, Consumer Safety Officer, Office of Enforcement

Ms. Sonal Vaid, General Attorney, Office of Chief Counsel

Mr. Mark Hackman, Consumer Safety Officer, Center for Food Safety and Applied Nutrition

Mr. Stewart Crumpler, Regulatory Officer, Center for Devices and Radiological Health

Ms. Christine Nelson, Supervisory Consumer Safety Officer, Office of Health and Industry Programs, Center for Devices and Radiological Health

Dr. Vernon Toelle, Math Statistician, Center for Veterinary Medicine

Ms. Karen Moksnes, Consumer Safety Officer, Office of Compliance, Center for Drug Evaluation and Research

Mr. Charles Ahn, Consumer Safety Officer, Office of Regional Operations

Ms. Jennifer Thomas, Associate Director for Policy, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research

The meeting was requested by the industry coalition to discuss the scope of 21 CFR Part 11. This meeting was a follow up to the one we had with the group in February of 2001. This meeting was intended to focus on the issue of scope, with attendance by a subgroup of the coalition.

Mr. Taylor explained that we wanted this meeting to focus on matters relating to the scope of part 11 that would affect individual industries in the coalition as well as all industries.

Mr. Bradley said his group did not expect final agency decisions at this meeting, but that he hoped to clarify some misunderstandings. He also said it was not industry's intent to avoid compliance with the rule but the coalition wanted to make known its concerns and difficulties.

Mr. Bradley explained that Mr. Loftus and Mr. Arora chair the coalition's sub-group on the subject of part 11's scope.

Our discussions then focused on the following points that the coalition prepared in a one-page document. Excerpts are quoted.

<u>What constitutes a required record?</u>

> "1. Our understanding of the regulation is that 21 CFR Part 11 applies to those records in electronic form, as explicitly defined in the predicate rules, that are created, maintained, and/or submitted in electronic form. As stated in the latter part of §11.1(b), it applies to those records set forth in agency regulations or those records submitted under the requirements

of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, when submitted in electronic form."

During our discussions the coalition representatives said that they generate a great number of electronic documents and records and were concerned with the high volume that would come under the rule.

We explained that for purposes of the scope of the rule, we made no distinction between document and record, or whether or not a record was signed. Ms. Vaid explained that we define record in a very broad legal sense.

We explained that a record could be required not only on a primary basis by explicit wording in a regulation or law, but also on a secondary basis. We gave the example of a standard operating procedure, explicitly required by regulation in which a firm says it will record and preserve certain information; the recorded information may not be explicitly identified in a regulation, but the firm imposes the requirement upon itself by virtue of its standard operating procedure. We explained that as a rule of thumb, if not having a record would be a violation of FDA law or regulation, the record would be considered required and would be covered by part 11 when in electronic form.

Mr. Bradley commented that not all records have a direct bearing on product quality and safety and that those that do not should not be covered by the rule. Mr. Taylor said that the significance of a required record would not affect its coverage under part 11, but could affect a firm's priority in bringing the relevant systems into compliance. Mr. Taylor emphasized that these were separate matters.

<u>Records held for short periods of time</u>

"2. We also understand that the regulation applies to required electronic records stored on durable media, such as magnetic disk or tape, and not to temporary records stored on non-durable media, such as flash memory in PDAs, or devices intended for short term data capture, such as programmable logic controllers and data loggers, which have little or no ability to provide audit trails or to export data to other systems in electronic form."

We explained that the question was really addressing the issue of audit trails, and not whether a record is covered by part 11. We commented that, as explained in the final rule preamble, the requirement for audit trails does not apply to actions of devices, but to actions of human operators. We explained that programmable logic controllers and data loggers that record information to required records without human intervention need not have audit trails, but they must meet other relevant portions of part 11.

We commented that whether or not the recording media was durable, and whether or not a system had the capacity to generate an audit trail did not determine part 11 applicability. We explained that the question appeared to relate to a preamble comment that clarified the agency's intent that audit trails need not capture every keystroke stored in a temporary buffer.

Changing the rule's scope via guidance

> "3. If and when there is an intent to extend the scope of the regulation to cover electronic records other than those explicitly required by the predicate rules then this should be accomplished via the normal rule making process and not through the issuance of guidance documents."

Mr. Taylor explained that any changes in the rule's scope would be made through notice and comment rulemaking, not by guidance. We added that, as explained above, the rule currently covers records in electronic form that FDA law or regulation require.

Records retention

> "4. Required records created, maintained and or/submitted in electronic form will also be archived on durable media in a manner ensuring that the records can be made available in human readable form. In addition to the required records, defined in item 1, other records submitted to the agency electronically will also be archived in an analogous manner."

We explained that how long an electronic record must be retained under part 11 is governed by predicate rule retention requirements. We commented that some regulations are silent on whether or not submitters must retain copies of what they submit. We said that if there were no retention requirement for a given submission, a firm would not have to keep a copy itself in any form, let alone an electronic copy, as otherwise required by part 11.

We commented that in our records retention guidance we expected to cover the concept of migrating electronic records from one computing platform to another.

When an audit trail begins

> "5. An electronic record is considered to be created, and then subject to a future audit trail, once it has been authenticated by the application of an electronic signature or by whatever authentication process is required for

the record, or as defined in a company's SOPs (Standard Operating Procedures)."

We commented that the question has to do with audit trails and not whether or not a given electronic record is subject to part 11. We said we will cover the issue of audit trails, and when they should commence, in a separate guidance document. We said, however, that both signed and unsigned records are covered by part 11. We commented that record creation is a process rather than an instant event and that part 11 controls are intended to build record reliability into that process.

Bringing large complex systems into compliance

Mr. Loftus commented that large organizations are having difficulties integrating different computing systems and getting them to function properly. He said these complexities can make it more challenging to bring such systems into part 11 compliance. He added that scaling up a public key infrastructure (PKI) was also more challenging for large establishments.

During our discussions we said we had heard some smaller firms say they have a relatively easy job of adapting to new systems and establishing a PKI based digital signature system. We added that smaller firms also said they thought larger firms would have greater resources that would help them adapt to changes.

Compliance policy

The coalition representatives commented that a report in the Washington Drug Letter had quoted a (female) FDA representative at a recent industry conference as saying FDA expected firms to be compliant by the end of the year, in light of fast emerging enabling software.

Mr. Taylor explained that the report was in error and that FDA's enforcement policy, as expressed in our Compliance Policy Guide, had not changed. He added that we are exercising a great deal of enforcement discretion, for now, although our expectations for industry compliance may increase as we publish industry guidance and clarify various issues.

The meeting concluded after about two hours.

DOC ID: Memo of Meeting033001f.doc
P. Motise 04/09/01; rev 06/11/01

cc: HFA-224
HFC-200
FDA Meeting Attendees